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231-503—66

In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 372

ALLAN DRUG CORPORATION, PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (Pet. 17–32) are reported at 357 F. 2d 713. The findings of fact and conclusions of law of the district court (R. 23–27) are not reported.

JURISDICTION

The judgment of the court of appeals was entered on February 18, 1966. A petition for rehearing was denied on April 29, 1966. The petition for a writ of certiorari was filed on July 20, 1966. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

The "grandfather clause" of the Drug Amendments of 1962 exempts from the requirement that promotional claims be supported by substantial evidence of effectiveness drugs commercially available on the date of enactment, if the drug was "intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day." The claims for the drug here involved—which were in use on the date of enactment—have been adjudged false and misleading, and labeling revision is required to bring the article into compliance with law. The question presented is whether the grandfather clause excuses the drug company from the requirement of proof of effectiveness of the revised labeling.

STATUTE INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act and of the Drug Amendments of 1962 are set forth in the Appendix, *infra*, pp. 11–13.

STATEMENT

This was a seizure action *in rem* under the Federal Food, Drug, and Cosmetic Act involving Halsion Tablets, a multi-vitamin preparation distributed by petitioner (R. 55, 120–121). The drug was alleged to be misbranded because its labeling made false and misleading claims regarding its effectiveness as a treatment for acne and pimples. After a trial, the district court found that the labeling contained repre-

sentations to prospective customers that were false and misleading (R. 26):

> (a) The "Halsion Plan" in and of itself is not an adequate and effective remedy for the treatment for acne and pimples.
>
> (b) There is not a unanimity of opinion in the medical profession as to the proven value of the "Halsion Plan", either including or excluding the taking of the Halsion pills, as an effective treatment for acne and pimples.
>
> (c) Neither the Halsion Plan nor the Halsion pills consist of "a revolutionary new vitamin formula for internal medication" in the treatment of acne and pimples. Vitamins are prescribed by some members of the medical profession as a part of the treatment for acne and pimples. The use of vitamins for this purpose began about thirty years ago.

The district court entered a decree of condemnation which adjudged the drug to be misbranded and directed that the drug be returned to the petitioner to be relabeled under the supervision of the Food and Drug Administration (R. 27–30). Paragraph 6 of that decree provided, in accordance with 21 U.S.C. 334(d) (R. 29), that:

> The Claimant shall not sell or dispose of said articles * * * in a manner contrary to the provisions of the Federal Food, Drug, and Cosmetic Act * * *.

One of the principal objections to the proposed labeling revisions was their failure to comply with the new-drug requirements of the law added by the Drug Amendments of 1962 (R. 52–53).

Nevertheless, on motion of petitioner, the district court entered an Order For Relabeling (R. 59–60) which decreed that the product may be relabeled and dispensed without compliance with the Drug Amendments of 1962 and approved labeling to be used for future promotion of the drug which permits continued and unqualified use of the original bottle and carton labels (R. 55), including a package insert which states in part (Pet. 22, n. 8):

> Halsion Tablets have been formulated to help treat mild cases of acne/pimples * * *.

This language was approved because of the district court's finding (R. 26–27) that:

> 4. The "Halsion Plan" may be of some benefit in mild cases of acne and pimples, and the measures prescribed in the Plan are used by some members of the medical profession, in whole or in part, in conjunction with other measures and treatments which the physician may deem to be indicated. There is no evidence that any members of the medical profession use or recognize the Halsion Plan in and of itself as an adequate and effective treatment for acne and pimples.

The Court of Appeals for the Tenth Circuit reversed, one judge dissenting. The Court held that, as a result of the labeling changes required by condemnation, the drug lost the immunity of the grandfather clause in the Drug Amendments of 1962. It stated (Pet. 27, 357 F. 2d at 719):

> [W]e construe the critical language of the Grandfather Clauses to exempt drugs not gen-

> erally recognized as effective if on the effective date of the Act the labeling contained the same representations concerning its use, and thus confine the exemptions to drugs intended solely for use under conditions prescribed on the effective date of the Act. * * *

Since the labeling approved by the district court after condemnation was not the same as the original labeling, the court ruled that the drug was no longer "intended solely for use under conditions prescribed on the effective date of the Act." Consequently, the grandfather clause no longer applied, and the drug ceased to be exempt from the "new drug" definition in 21 U.S.C. 321(p)(1) and could be marketed only on the basis of proven effectiveness in compliance with 21 U.S.C. 355 (Pet. 27, 30, 357 F. 2d at 719, 721).

ARGUMENT

The central purpose of the Drug Amendments of 1962 is to prevent exploitation of the consumer through unproven remedies of dubious value. To this end, the Amendments establish a procedure for proving the effectiveness of new drugs. Petitioner's Halsion Tablets are plainly a new drug within the meaning of the Amendments (see pp. 8–9, *infra*), and the only question is whether this drug is exempt from the new-drug requirements by virtue of Section 107(c)(4)—the "grandfather clause"—of the Amendments. The court below correctly found that it was not. As the court of appeals rightly pointed out (Pet. 25, 357 F. 2d at 718), "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against

the one who invokes it." It would be improper to read "an exception to an important provision safeguarding the public welfare with a liberality which more appropriately belongs to enforcement of the central purpose of the Act." *United States* v. *Dotterweich,* 320 U.S. 277, 284. The exemption of Section 107(c)(4) applies only if the drug is intended solely for use under conditions recommended in the labeling of the drug at the time the Amendments were passed. Since the labeling of Halsion Tablets was found to be false and misleading, the drug may no longer be sold for use as suggested in the labeling that was in force at the time of the enactment of the Drug Amendments, and it is therefore not within the terms of the exemption.

Petitioner contends that the court of appeals' construction will deter drug manufacturers from voluntarily changing their labeling to make it more accurate and less misleading. But that is not this case. Petitioner's labeling was found in a judicial proceeding to be false and misleading; it was only under compulsion of law that the labeling was changed. We submit that a change of labeling required because of a manufacturer's violation of law is not a shield against compliance with the requirements of the Drug Amendments.

Petitioner also contends that the decision below improperly limits the district court's discretionary power to permit the salvage, rather than destruction, of condemned drugs. However, the power of the district court to return a condemned drug to the

manufacturer is operative only where the drug can be brought into full and unequivocal compliance with all of the provisions of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. 334(d); *United States* v. *Kent Food Corp.*, 168 F. 2d 632, 634–635 (C.A. 2), certiorari denied, 335 U.S. 885; *Research Laboratories, Inc.* v. *United States*, 167 F. 2d 410, 422–423 (C.A. 9), certiorari denied, 335 U.S. 843; *United States* v. *716 Cases . . . Del Comida Brand Tomatoes*, 179 F. 2d 174, 175 (C.A. 10). The key limitation of the district court's discretionary power to permit salvaging of a condemned article is the statutory condition that the article is "to be destroyed or *brought into compliance with the provisions of this chapter.*" 21 U.S.C. 334(d) (emphasis added). The scope of the district court's discretion is not fixed as of 1938 when Section 334(d) was enacted, but may be affected by any legislative change in the "provisions of this chapter" though such change may not make specific reference to Section 334(d). When the district court exercised its discretionary power in this case on October 2, 1964 (R. 59), its power was limited by the Drug Amendments of 1962 as well as all other amendments to the basic Act of 1938 that were in effect on October 2, 1964.

Petitioner alleges but in no way shows a conflict between the decision below and *Buticaps, Inc.* v. *United States* (Pet. App. C, 252 F. 2d 634 (C.A. D.C.)). Both decisions hold that the courts rather than the administrative agency must make the final decision as to the terms and conditions of salvage-

ability of a condemned product; otherwise, they are completely unrelated.[1] In the instant case the court of appeals held only that the district court had exceeded its statutory authority when it authorized a salvage operation which did not conform to the 1962 law. No such issue was involved in *Buticaps*.

Petitioner contends finally that the decision below deprives it of property without due process of law. But its drug was condemned by the district court only after a full trial in which the drug was found to be misbranded by reason of false and misleading labeling. By the judicial process, petitioner's pills were adjudicated to be "outlaws of commerce" (*Hipolite Egg Co.* v. *United States*, 220 U.S. 45, 58) and petitioner then lost the right to regain the property. Nor is there any merit to the suggestion that the question of the effectiveness of Halsion Tablets was not adequately canvassed. Under the Drug Amendments, a drug whose effectiveness is not generally recognized by qualified experts is a "new drug" and it may not be marketed commercially until its sponsor has demonstrated its effectiveness by substantial evidence in an administrative proceeding. 21 U.S.C. 355. No further hearing is required to demonstrate that Halsion Tablets are not generally recognized by

[1] The dissenting opinion is mistaken in stating that the Food and Drug Administration "took the position that no salvage was possible under its construction of the Act." (Pet. 29, 357 F. 2d at 720–721). In fact the agency pointed out that there were three possible methods of salvage (R. 54), and it indicated a readiness to consider any proposals petitioner might make for bringing the article into compliance with the Act (R. 53).

qualified experts as effective for the purposes stated in the revised labeling, namely (1) "to help treat mild cases of acne/pimples," and (2) "for the management and care of mild cases of acne, pimples, blackheads and oily skin" (Pet. 22, n. 8; 357 F. 2d at 717). Condemnation of the drug was predicated upon an ample showing that it is not an adequate and effective remedy for acne and pimples. The district court's finding in approving the revised labeling that "the Halsion Plan may be of some benefit in mild cases of acne and pimples" (R. 26) is merely a conjectural statement of possible benefit—yet it reflects the very best that can be said for the drug. The evidence is clear that the drug is not generally recognized by qualified experts as effective in the treatment of any kind of acne and pimples, mild or severe.[2]

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[2] Dr. Cornbleet, an outstanding dermatologist, testified that Vitamin A has had its vogue in the treatment of acne and that the vast majority of doctors no longer use it (R. 143). Dr. Buchholz testified that Vitamin A was not even mentioned as a treatment for acne at the last meeting of the International Congress on Dermotology (R. 100). Dr. Perlstein, called by the defense, testified (R. 186): "I don't think the medical profession knows the Halsion Plan." She also testified (R. 187): "There is a definite controversy among us dematologists about the use of vitamins in the internal treatment of acne vulgaris." She stated she knew of no controlled clinical studies that have been performed by the use of Halsion Tablets (R. 188). The existence of such a controversy alone establishes that the drug is not "generally recognized" as effective by qualified experts and "brings the seized articles clearly within the statutory definition of a new drug." *United States v. 354 Bulk Cartons * * * Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 853 (D. N.J.).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 1966.

APPENDIX

Section 107(c)(4) of the Drug Amendments of 1962, 76 Stat. 789 provides:

> In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

Section 201 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1041, as amended, 21 U.S.C. 321, provides:

> For the purposes of this Act—
>
> * * * * *
>
> (p) The term "new drug" means—
>
> (1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety *and effectiveness* of drugs, as safe *and effective* for use under the conditions prescribed, recommended, or suggested in the labeling thereof * * *.

(Italicized matter added by 1962 amendments.)

Section 304 of the Act, 21 U.S.C. 334, provides:

> (a) Any article of * * * drug * * * that is * * * misbranded * * * shall be liable to be * * * condemned * * *.
>
> * * * * *

(d) Any * * * drug * * * condemned under this section shall * * * be disposed of by destruction or sale * * * *Provided,* That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter under the supervision of an officer or employee duly designated by the Secretary * * *.

Section 502 of the Act, 21 U.S.C. 352, provides:

A drug * * * shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Section 505 of the Act, 21 U.S.C. 355, provides:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use *and whether such drug is effective in use;* (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing,

and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug. (Italicized matter added by 1962 amendments.)

U.S. GOVERNMENT PRINTING OFFICE: 1966